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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/462,576 05/25/00 HAVKIN-FRENKEL <u>;</u>; 13252-090Ci **EXAMINER** HM12/0907 SAUL EWING REMICK & SAUL ART UNIT PAPER NUMBER CENTRE SQUARE WEST 1500 MARKET STREET 38TH FLOOR 1638 DATE MAILED: PHILADELPHIA PA 19109

09/07/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

•	· · · · · · · · · · · · · · · · · · ·	Application No.	Applicant(s)
Office Action Summary		09/462,576	HAVKIN-FRENKEL ET AL.
		Examiner	Art Unit
		Cynthia Collins	1638
The MAILING DATE of this communication appears on the cover she t with the c rrespondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status			
1)⊠)⊠ Responsive to communication(s) filed on <u>05 July 2001</u> .		
2a) <u></u> ☐	This action is FINAL . 2b)⊠ Thi	s action is non-final.	
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4)⊠ Claim(s) <u>1-10</u> is/are pending in the application.			
4a) Of the above claim(s) is/are withdrawn from consideration.			
5) Claim(s) is/are allowed.			
6)⊠ Claim(s) <u>1-10</u> is/are rejected.			
7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
9)☐ The specification is objected to by the Examiner.			
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.			
12) The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. §§ 119 and 120			
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).			
a) All b) Some * c) None of:			
1. Certified copies of the priority documents have been received.			
2. Certified copies of the priority documents have been received in Application No			
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).			
 a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. 			
Attachment(s)			
2) Notice	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal P	(PTO-413) Paper No(s) atent Application (PTO-152)

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-11, in Paper No. 8 is acknowledged. Claims 12-30 have been cancelled.

- 2. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).
- 3. Misnumbered claims 9, 10, and 11 been renumbered 8, 9, and 10.
- 4. Accordingly, after the renumbering of the claims, Group I constitutes claims 1-10.
- 5. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

6. An initialed and dated copy of Applicant's IDS form 1449, Paper No. 5, is attached to the instant Office action.

Claim Objections

7. Claim 1 is objected to because of the following informalities: *Vanilla planifolia* is misspelled as "*Vanillin planifolia*". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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9. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for improving production of vanillin in cultured *Vanilla planifolia* cells in cultured *Vanilla planifolia* cells by supplementing the culture with 3% malic acid alone, 1 mM 3,4-dihydroxybenzaldehyde alone, or 30 ug/mL glycosylated lysozyme elicitor protein alone, does not reasonably provide enablement for a method for improving production of vanillin in cultured *Vanilla planifolia* cells in cultured *Vanilla planifolia* cells by supplementing the culture with malic acid, 3,4-dihydroxybenzaldehyde, citric acid, pyruvic acid, oxaloacetic acid, succinic acid, glycosylated lysozyme elicitor protein, and any combination thereof, . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

- 10. The claims are drawn to a method for improving production of vanillin in cultured *Vanilla planifolia* cells by supplementing the culture with malic acid, 3,4-dihydroxybenzaldehyde, citric acid, pyruvic acid, oxaloacetic acid, succinic acid, glycosylated lysozyme elicitor protein, and any combination thereof. The claims are also drawn to cultured *Vanilla planifolia* cells.
- 11. The specification only discloses a method for improving vanillin production in cultured *Vanilla planifolia* cells by supplementing the culture with 3% malic acid alone (page 29 *Table* 6), 1 mM 3,4-dihydroxybenzaldehyde alone (page 26 *Table 1*), or 30 ug/mL glycosylated lysozyme elicitor protein alone (page 29 *Table 5*). The specification does not teach whether any other compound, or any combination of compounds, will improve production of vanillin in cultured *Vanilla planifolia* cells.

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12. Guidance for making and using the claimed invention is necessary for enablement because the effect of different compounds on the production of vanillin in cultured *Vanilla planifolia* cells is highly unpredictable. Rao et al. (Journal of the Science of Food and Agriculture, February 2000, Vol. 80, No. 3, pages 289-304) teach that different types of phytohormones and different types of vanillin precursors can positively or negatively affect the production of vanillin in cultured *Vanilla* cells (page 296, column 2, first full paragraph to page 293, column 1, first paragraph).

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- 13. Given the unpredictability of a compound or combination of compounds improving vanillin production in cultured cells, the absence of guidance in the specification for making and using the claimed products and methods, the lack of working examples, and given the breadth of the claims which encompass all methods for improving the production of vanillin in cultured *Vanilla planifolia* cells by supplementing the culture with any amount and any combination of malic acid, 3,4-dihydroxybenzaldehyde, citric acid, pyruvic acid, oxaloacetic acid, succinic acid, and glycosylated lysozyme elicitor protein, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.
- 14. The following is a quotation of the second paragraph of 35 U.S.C. 112:
 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 15. Claims 1, 7, and 9-10, and claims 2-6 and 8 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 16. Regarding claims 1 and 7, the phrase "glycosylated lysozyme" in claim 1 and the phrase "glycosylated lysozyme elicitor" in claim 7 render the claim indefinite because it is unclear what

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the relationship is between the "glycosylated lysozyme" of claim 1, the "glycosylated lysozyme elicitor" of claim 7, and the "glycosylated lysozyme elicitor protein" of the instant specification (page 12 lines 12-17, for example).

17. Regarding claims 9-10, the phrase "at least" renders the claims indefinite because it is unclear how much vanillin production is encompassed by the claims.

Claim Rejections - 35 USC § 102

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 18. Claims 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Knuth et al (US 5,057,424, 15 October 1991, Applicant's IDS).
- 19. The claims are drawn to cultured *Vanilla planifolia* cells produced by the method of claim 1, cultured *Vanilla planifolia* cells which produced at least twice as much vanillin as equivalent unsupplemented cells, and cultured *Vanilla planifolia* cells which produced at least twice as much vanillin as equivalent unsupplemented cells.
- 20. Knuth et al. teach cultured *Vanilla planifolia* cells (column 13 column 15). Knuth et al. also teach that the amount of vanillin produced by cultured *Vanilla planifolia* cells is variable (column 15 lines 55-60). The claimed cultured *Vanilla planifolia* cells do not differ from the cultured *Vanilla planifolia* cells taught by Knuth et al.
- 21. Accordingly, claims 8-10 are anticipated by Knuth et al.

Remarks

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC September 4, 2001

ELIZABETH F. McELWAIN PRIMARY EXAMINER GROUP 1800

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